UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,292	05/09/2005	Karen Silence	A0848.70004US00	1144

23628 7590 08/05/2008

WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
08/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,292	SILENCE ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,8,15-27,46,52,53 and 64-67* is/are pending in the application.

4a) Of the above claim(s) *17-27,52 and 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,8,15,16,46 and 64-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/06, 12/14/06, 6/4/07, 8/9/07, 3/12/08, 4/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response and amendments received March 3 and May 15, 2008 are acknowledged.

Claims 3, 4, 6, 7, 9-14, 28-45, 47-51, and 54-63 have been canceled.
Claims 1, 2, 5, 8, 20-23, 46, and 52 have been amended.
Claims 64-67 have been added.
Claims 1, 2, 5, 8, 15-27, 46, 52, 53, and 64-67 are pending in the instant application.

Applicant's election with traverse of Group 1, methods of administering single domain antibodies that bind TNFα, in the reply filed on March 3, 2008 is acknowledged. The traversal is on the ground that the invention has been amended to recite that the inventive concept is non-invasive delivery of therapeutic polypeptides and that the claims should be grouped based upon this criteria rather than antigen specificity. This is not found persuasive because oral delivery of therapeutic polypeptides, such as antibodies, is known in the art. See for example US Patents 5,871,731, 6,395,273, and 6,605,276. Further, it is the identity of the antigen bound by the administered peptide that determines what disease and disorders will or will not be effectively treated by the recited methods. For example, anti-IgE antibodies are not useful in treating an ulcerative colitis patient.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-27, 52, and 53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on March 3, 2008.

Claims 1, 2, 5, 8, 15, 16, 46, and 64-67 are under examination in this office action.

Specification

2. Applicant's amendments to the specification received May 15, 2008 to insert SEQ ID numbers is acknowledged.

The title and abstract are objected to because neither disclose the subject matter of the instant claimed invention, i.e. administering anti-TNFα antibodies.

Priority

Applicant is reminded that the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/425,063, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application in that it does not disclose anti-TNFα antibodies although it does disclose oral administration of antibodies.

Applicant has also claimed priority to 60/425,073, and this provisional application does disclose anti-TNFα antibodies as well as oral administration. However, the only inventor listed on the provisional application is Hans De Haard, a person who is not named as an inventor in the instant utility application. As per MPEP 1893.03(c), part IV,:

> In order for a national stage application (of international application "X") to obtain benefit under 35 U.S.C. 119(e) of a prior U.S. provisional application, the national stage application must comply with the requirements set forth in 37 CFR 1.78(a)(4) through 37 CFR 1.78(a)(6). Public Law 106-113 amended 35 U.S.C. 119(e) to eliminate the copendency requirement for a nonprovisional application claiming benefit of a provisional application. 35 U.S.C. 119(e)(2) as amended became effective on November 29, 1999 and applies to provisional applications filed on or after June 8, 1995. 37 CFR 1.78(a)(4) requires that the prior provisional application must be entitled to a filing date as set forth in 37 CFR 1.53(c),

and the basic filing fee set forth in 37 CFR 1.16(d) must be paid on the provisional application within the time period set forth in 37 CFR 1.53(g). **Additionally, the provisional application must name as an inventor at least one inventor named in the later filed international application "X" and disclose the named inventor's invention claimed in at least one claim of the national stage application in the manner provided by the first paragraph of 35 U.S.C. 112.** The national stage application must contain a reference to the provisional application (either in an application data sheet (37 CFR 1.76) or in the first sentence(s) of the specification), identifying it as a provisional application, and including the provisional application number (series code and serial number). The required reference to the earlier provisional application must be submitted within the time period provided by 37 CFR 1.78(a)(5)(ii). This time period is not extendable. However, if the entire delay, between the date the claim was due under 37 CFR 1.78(a)(5)(ii) and the date the claim was filed, was unintentional, a petition under 37 CFR 1.78(a)(6) may be filed to accept the delayed claim. If the provisional application was filed in a language other than English, ** an English-language translation of the non-English language provisional application and a statement that the translation is accurate >will be required. See MPEP § 201.11, subsection VI.< If the translation and statement that the translation is accurate were not * filed in the provisional application or in the later-filed national stage application >before November 25, 2005<, applicant will be notified and given a period of time within which to file an English-language translation and a statement that the translation is accurate> in the provisional application, and a reply in the national stage application that the translation and statement were filed in the provisional application<. Failure to timely reply to such a notice will result in abandonment of the national stage application. See 37 CFR 1.78(a)(5)(iv).

As such, the priority claim to application 60/425,073 is improper. Note further that Hans De Haard is not an inventor listed for PCT/BE03/00190 which published as WO 2004/041867 A2.

Therefore, the claims under examination have not been grated the priority date of the US provisional applications.

Information Disclosure Statement

3. The IDS forms submitted 9/11/06, 12/14/06, 6/4/07, 8/9/07, 3/12/08, and 4/28/08 are acknowledged and have been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 5, 8, 46, and 64-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has claimed broad methods of administering single domain antibodies to treat disorders. Neither the antigenic targets bound by the administered antibodies, nor the diseases and disorders being treated are recited in the instant claims.

It is well known in the art that antibodies bind epitopes within a target antigen and do not bind other unrelated epitopes in other antigens. For example, an antibody that binds IgE would not bind some other antigen, such as TNFα. It is also known in the art that specific antigens are indicative of specific diseases. For example, pemphigus vulgaris is characterized by skin blisters caused by autoantibodies that bind desmogleins 1 and 3, cadherins that are necessary for cell-cell adhesion of skin keratinocytes (Amagai, Mo, J. Dermatol. Sci., 1999, 20:92-102, see entire document, particularly the abstract and introduction) whereas allergic reactions cause inflammation due to the release of soluble mediators from mast cells following antigen-induced crosslinking of IgE molecules bound to the surface of said mast cells (Janeway et al., Immunobiology, third edition, 1997, page 11:11). As such, anti-IgE antibodies are known to be useful in treating allergy, but would not be effective in treating pemphigus vulgaris. Thus, it is clear that only antibodies directed against a specific target will be effective in treating a particular given disease. The instant claims provide no guidance as to what targets for antibody binding are to be used in treating any particular disease. As such, a skilled artisan would be required to perform unpredictable experimentation in figuring out which antigenic targets are useful in which diseases prior to practicing the claimed methods.

Therefore, given the breadth of the claims, the lack of guidance and direction, and the teachings of the art, a skilled artisan would be unable to practice the instant claimed methods without performing additional, unpredictable experimentation.

6. Claims 1, 2, 5, 8, 15, 46, and 64-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claimed methods recite administering anti-target single domain antibodies to patients to treat unspecified disorders. Thus the size of the genus of antibodies used in the methods is large and reasonably unknowable since it encompasses antibodies to all possible targets for all possible diseases. Dependent claim 15 narrows the scope somewhat it that it recites that the target is TNFα and that the disorder is inflammation.

The guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, January 5, 2001, see especially page 1106 column 3).

In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412) 19 F. 3d 1559, the court held that disclosure of a single member of a genus (rat insulin) did not provide adequate written support for the claimed genus (all mammalian insulins). In this same case, the court also noted: "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re

Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

The court has further stated that "Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

As discussed above, there is no correlation between the structural properties of the recited antibody (i.e. what target the antibody binds) and its functional properties (what disorders are treated), and the size of the genus encompassed by the claims is conceivably unknowable. Dependent claim 15 limits the target antigen to TNFα, yet the source of the TNFα and the subject to whom the antibodies are administered is not recited. While the sequence of the TNFα antigen is known for some mammals, its is not known for all animals yet the breadth of the claim reads on administering antibodies that bind the entirety of the genus of TNFα polypeptides to any subject. Further, the specification indicates that "targets" comprise not only wild type sequences but additionally comprises fragments, truncations, insertions, deletions and mutations of said wild type targets, with the number of insertion, deletions and substitutions being up to 70 (see particularly page 15). Since all TNFα antigens from all species are not known, it is not reasonable that applicant is in possession of antibodies that bind the genus of all TNFα antigens, especially when the target "TNFα" further comprises a large number of unknown, non-naturally occurring sequences. Note that the single domain antibodies consisting of SEQ ID NOs:12-14 are not representative of this genus of anti-TNFα antibodies since they cannot reasonably bind all naturally occurring and mutated polypeptides that the specification discloses are comprised by the term "TNFα".

Note that the discussion of "targets" comprising mutations and other variations is not limited to TNFα and encompasses all targets. As such, it is difficult to discern from the specification what is and what is not a "target".

Therefore, it appears that the broad genus of anti-"target" antibodies recited in the claimed methods lack adequate written description because there does not appear to be any correlation between structure and function for all "targets" and disorders. Further, even the target "TNFα" lacks adequate written description based upon the breath that this genus encompasses as discussed above. As such a skilled artisan would reasonably conclude that applicant was not in possession of the claimed genus of treatment methods at the time the instant application was filed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claim recites "corresponds to a sequence represented by any of SEQ ID NOs:12 to 14." What are the metes and bounds of this claim? Does the method require the use of an antibody that consists of SEQ ID NO:12, 13, or 14? Does an antibody that "corresponds to a sequence represented by" allow for amino acid substitutions, deletions, and inversions such that the antibody used in the method differs from SEQ ID NOs:12, 13, or 14? If the language allows for sequence variation, how much is permitted? To clarify the scope of the claim, it is suggested that the "corresponds to a sequence represented by" be replaced with the well established terms "comprising" or "consisting of" to limit SEQ ID NOs:12-14 if that is what the current recitation is intended to mean. If amino acid differences are meant to be encompassed by the scope of the claim, this fact should be made explicitly clear in the claim through the use of terms such as mutation, substitution, and their ilk. Remember that any such claim terminology must be supported by the disclosure as originally filed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 5, 8, 15, 46, and 64-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Salfeld et al. (WO 97/29131).

Salfeld et al. disclose methods of administering antibodies that bind human TNFα to treat numerous diseases and disorders, including intestinal disorders including Crohn's disease and ulcerative colitis (see entire document, particularly the abstract, the paragraph spanning pages 5 and 6, and page 39). The antibodies of Salfeld et al. are disclosed as being administered in oral formulations such that inactivation of the antibody is prevented (see particularly page 29). Anti-TNFα antibodies used in the methods of Salfeld comprise single chain Fv (see particularly lines 17-24 of page 3 and page 8). scFV are single domain antibodies as defined in lines 1-16 of the instant specification. Note that the human antibodies of Salfeld et al. are homologous to *Camelidae* antibodies.

Therefore, the prior art anticipates the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 2, 5, 8, 15, 46, and 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kink et al. (WO 99/64069, see entire document) in view of Muyldermans (US2007/0031424 A1, see entire document).

Kink et al. disclose methods of treating inflammatory bowel diseases such as ulcerative colitis and Crohn's disease by oral administration of anti-TNFα antibodies (see entire document, particularly the abstract, pages 5-7, and examples 1, 2, and 6-8). This disclosure differs from the instant claimed invention in that the orally administered antibodies are not single domain antibodies.

Muyldermans et al. disclose the administration of camelid single domain heavy chain antibodies for the treatment of diseases including Crohn's disease and ulcerative colitis (see entire document, particularly the abstract and paragraphs 191 and 193). Such antibodies are further disclosed as being humanized (see particularly paragraphs 125 and 126). Single domain antibodies are disclosed as comprising the advantages of improved expression levels, stability, affinity and solubility as compared with other antibodies (see particularly paragraph 217).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the anti-TNFα antibodies used in the methods of Kink et al. to be single domain antibodies in order to gain the advantages of improved expression, solubility, stability and affinity that single domain antibodies enjoy as compared to other antibodies as disclosed by Muyldermans et al.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1, 2, 5, 8, 15, 46, and 64-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 28, 30, 34, 36 and 39 of copending Application No. 10/534,348. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims anticipate the instant invention. Specifically, the copending claims recite the oral administration of single domain antibodies that bind TNFα to patients for treatment of specific diseases such as Crohn's disease and ulcerative colitis. As such they are of narrower scope and thus anticipate the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1, 2, 5, 8, 15, 46, and 64-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 15 of copending Application No. 10/534,349. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims anticipate the instant invention. Specifically, the copending claims recite the oral administration of a composition comprising a single domain antibodies that binds TNFα

and a single domain antibody that binds another target to patients in need thereof for treatment of inflammatory disorders. As such the copending claims are of narrower scope and thus anticipate the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1, 2, 5, 8, 46, and 64-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-23, 26, and 28 of copending Application No. 10/553,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims anticipate the instant invention. Specifically, the copending claims recite the oral administration of single domain antibodies that bind the target EGFR to patients in need thereof for treatment of disease. As such the copending claims are of narrower scope and thus anticipate the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1, 2, 5, 8, 15, 46, and 64-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 21, 23, 24, 44, 45, 47, 48 of copending Application No. 11/788,832 in view of Salfeld et al. (WO 97/29131). The copending claims recite the administration of single domain antibodies that bind TNFα for the treatment of various disorders such as Crohn's disease and ulcerative colitis. These claims differ from the instant invention in that they do not recite that the single domain antibodies are administered orally. Salfeld et al. disclose that single domain antibodies specific for TNFα are to be administered orally and thus the instant claimed invention would have been obvious to a person of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection.

18. Claims 1, 2, 5, 8, 15, 46, and 64-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 50-59 and 61-67 of copending Application No. 11/636,300 in view of Salfeld et al. (WO 97/29131). The copending claims recite the administration of single domain antibodies that bind TNFα for the treatment of rheumatoid arthritis, an inflammatory disease. These claims differ from the instant invention in that they do not recite that the single domain antibodies are administered orally. Salfeld et al. disclose that single domain antibodies specific for TNFα are to be administered orally and thus the instant claimed invention would have been obvious to a person of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection.

19. No claims are allowable.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Primary Examiner
Art Unit 1644

/Michael Szperka/
Primary Examiner, Art Unit 1644